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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,034	09/25/2003	Thomas A. Wynn	22058-519 CIP DIV2	6681

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/671,034	WYNN ET AL.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,16-21,24-28 and 31-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,16-21,24-28 and 31-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1a. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 24 October 2006 has been entered.

Status of Claims:

1b. Claims 13, 16-21, 24-28, 31-52 are pending and under consideration.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted 24 October 2006 has been received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Priority:

3. Based on the information given by Applicants and an inspection of the patent applications and for prior art purposes, the current application is afforded the effective filing date of 29 November 1999, which is the filing of the parent application 09/301,808.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 11/29/1999, which specifically supports

the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 1/29/1999.

Claim rejections-35 USC § 103:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 13, 16-21, 24-28, 31-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiaramonte et al (The Journal of Immunology, Vol. 162, pages 920-930, January 1999) in view of Feldmann et al, (Springer Seminars in Immunopatholgoy, Vol. 20, pages 211-228, 1998).

Instant claims 13 and 21 are drawn to a method of treating tissue fibrosis or a method of inhibiting formation of tissue fibrosis in a mammalian subject by administering an antibody to IL-13 or a fragment of said antibody and a pharmaceutically acceptable

carrier. Dependant claims further limit the invention in terms of the type of tissue fibrosis and modes of administration.

Chiaramonte et al teach that IL-13 is an important mediator of Th2 mediated inflammation and plays a role in eliciting IgE responses by schistosome eggs and that chronic parasite egg-induced granuloma formation (fibrosis) can lead to the development of severe disease in humans, (see abstract and page 929, column 2). Chiaramonte et al also show that in-vivo blockade of IL-13, using a soluble IL-13R α2-Fc fusion protein, significantly reduced the size of pulmonary granulomas in un-sensitized as well as egg-sensitized mice, (see page 921, column 2 and figure 4).

Feldmann et al review the rationale for anti-TNFα therapy in rheumatoid arthritis and discuss several anti-TNFα antibodies in clinical trials, (see abstract). Feldmann et al state that the use of anti- TNF therapies are well tolerated and that there is often rapid improvement in patients, (see page 224). Feldmann et al maitain that the benefits of the anti-TNFα therapy are widespread with reductions in all signs and symptoms, and are strikingly reproducible with a variety of biological agents. The authors suggests that the effort expended in the laboratory to understand the pathophysiology of cytokines will be amply repaid in the clinic, (see page 224, last paragraph).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to devise the claimed method by following the combined teachings of the Chiaramonte et al and Feldmann et al references, because Chiaramonte et al teach that IL-13 plays a significant role in the pathogenesis of tissue fibrosis and that blocking IL-13 effects with the IL-13 antagonist IL-13R α2-Fc fusion

protein significantly reduced the size of pulmonary fibrosis, while Feldmann et al teach that using antibodies to block the activity of cytokines is a feasible endeavor.

There would have been an expectation of success to antagonize IL-13 activity by using an antibody against IL-13 for the treatment of tissue fibrosis, because, Feldmann et al teach that at the time the instant invention was made, therapeutic antibodies have achieved great success, and anti-cytokine antibodies have been used successfully and Chiaramonte et al teach that IL-13 is involved in the development in tissue fibrosis and that blocking IL-13 effects significantly reduced the size of pulmonary fibrosis.

One of ordinary skill in the art would have been motivated to combine the teachings of the Chiaramonte et al and Feldmann et al references, because tissue fibrosis can lead to the development of severe disease in humans.

Conclusion:

4. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud
Patent Examiner
Art Unit 1647
06 December 2006

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